REMARKS

This Response is to the final Office Action mailed on June 15, 2009. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. SMDI-5966 (112713-1362) on the account statement.

Claims 1 to 11 and 13 to 45 are pending in the application. Claim 12 was previously canceled and Claims 31 to 44 were previously withdrawn from consideration. In response, Claims 1, 16 and 23 have been amended. The amendments add no new matter and are supported in Applicants' specification at, for example, page 10, lines 16 to 22 and page 12, lines 5 to 12.

In the Office Action, Claim 6 was rejected under 35 U.S.C. §112, second paragraph. Claims 1, 3, 7 to 10, 14 to 17, 19, 23, 24, 26, 27, 30 and 45 were rejected under 35 U.S.C. §102(e) as being unpatentable over U.S. Publication No. 2006/0149192 to Deniega et al. ("*Deniega*"). Claims 2, 4, 22, 28 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Deniega* in view of U.S. Patent No. 4,488,877 to Klein et al. ("*Klein*"). Claims 11, 13, 20 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Deniega* in view of U.S. Publication No. 2004/0199110 to Basta ("*Basta*"). Claims 6 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Deniega* in view of U.S. Publication No. 2005/0245897 to Bolduc et al. ("*Bolduc*"). Claim 18 was rejected under 35 U.S.C. §103(a) as being unpatentable over *Deniega* in view of U.S. Patent No. 4,479,792 to Lazarus et al. ("*Lazarus*").

Regarding the §112, second paragraph rejection, the Office Action asserts that "the plug" of Claim 6 lacks antecedent basis. In response, Applicants amend Claim 6 to depend from Claim 2 rather than Claim 1. Claim 2, by reciting "a plug," provides the necessary antecedent basis. Applicants submit therefore that Claim 6 meets the requirements of 35 U.S.C. §112, second paragraph. Applicants accordingly request that this rejection be withdrawn.

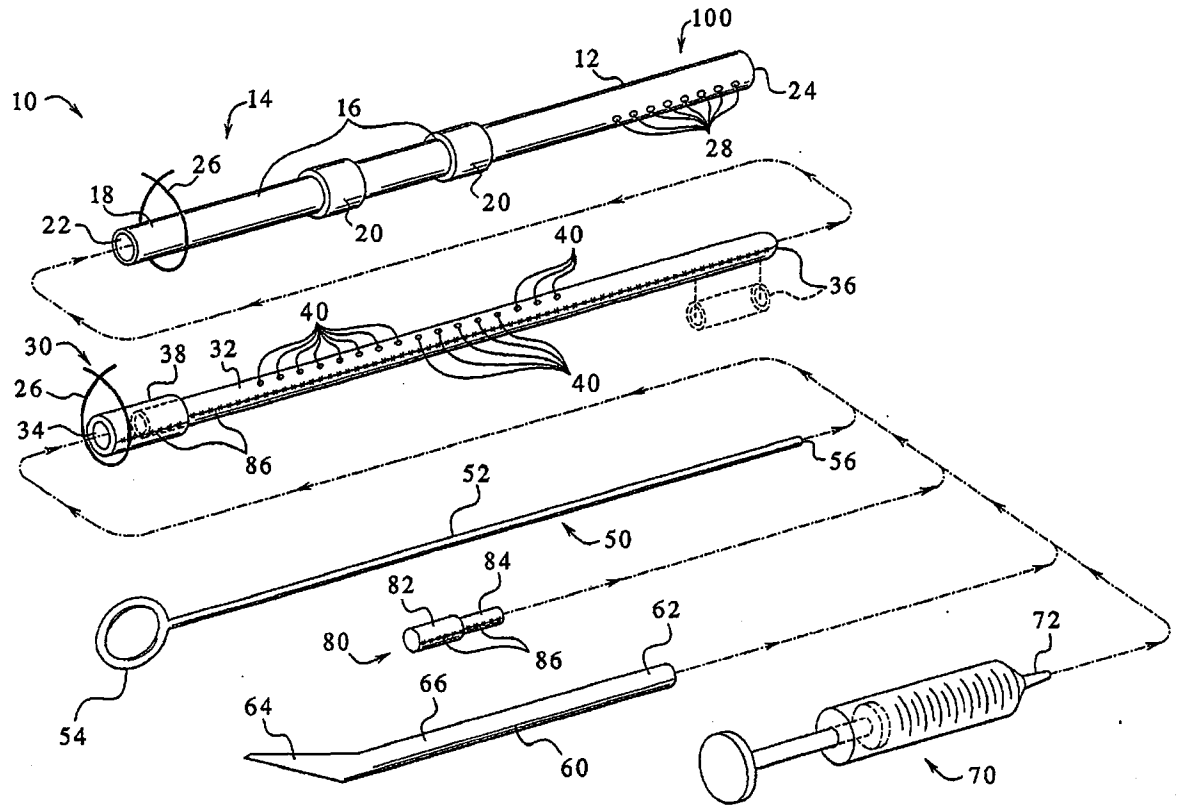
Regarding the anticipation rejection of Claims 1, 3, 7 to 10, 14 to 17, 19, 23, 24, 26, 27, 30 and 45, Applicants submit that *Deniega* fails to disclose or suggest an insert extending along a passageway defined by an interior surface of a catheter, the insert comprising a larger diameter portion and an elongated portion having an exterior surface, the exterior surface of the elongated portion of the insert sized relative to the interior surface of the catheter to define a gap between the catheter and the elongated portion of the insert, the larger diameter

portion of the insert sized to achieve a snug fit between the interior surface of the catheter and the larger diameter portion of the insert as required, in part, by independent Claims 1, 16 and 23. Rather than teaching the combination of a catheter and an insert within the catheter, *Deniega* only teaches a catheter that includes a tube portion enclosing a porous membrane (see, *Deniega*, FIGS. 5 to 7 and 13 to 18) or a coiled spring (see, *Deniega*, FIGS. 9 to 11). Therefore, *Deniega* is deficient for failing to disclose or suggest both a catheter and a separate insert or obstructor positioned within the catheter.

The Office Action asserts, however, that inner elongated tubular porous membrane 54 of catheter 50 reads on the insert of the present claims and that membrane 54 inherently has the insert apertures of the present claims because of its porous structure. See, Office Action, page 2, #1. Applicants note however that the claims recite that the second plurality of apertures are formed specifically on the elongated portion of the insert near the extraperitoneal end of the insert. By contrast, *Deniega* teaches membrane 54 generally formed along the infusion section. See, *Deniega*, paragraph [0054]. Therefore, even if porous membrane 54 inherently had apertures, membrane 54 of *Deniega* would provide these apertures in the infusion section (or intraperitoneal portion of the catheter), rather than near the extraperitoneal end of the insert as claimed.

To understand better this distinction between *Deniega* and the present claims, FIG. 1 of the present application is included below to provide an example of the location of the insert apertures 40 relative to intraperitoneal portion 12 of catheter 10 and extraperitoneal end 34 of insert 30.

FIG. 1 of the present application



As is apparent for the above drawing, side apertures 40 of insert 30 are specifically located near the extraperitoneal end 34 of insert 30 (or the extraperitoneal portion 16) of catheter 10, while apertures 28 of catheter 10 are located on the intraperitoneal portion 12 of catheter 10 (or near the intraperitoneal end 36 of insert 30).

Applicants provide the secondary plurality of apertures 40 near extraperitoneal end 34 of insert 30 to allow injected hepanized saline (a) to fill the inner cavity defined by elongated tube portion 32 of insert 30 to prevent fibrin, protein, etc. from entering insert 30, (b) to fill the gap residing between the outer surface of insert 30 and the inner surface of catheter 10 to help keep fibrin, protein, etc. from entering catheter 10 through at least the first plurality of apertures 28, and (c) provide a lubricant along the exterior of insert 30 to allow for easy removal from within catheter 10. See, Applicants' specification, page 12, lines 2 to 9 and page 13, lines 16 to 24.

By contrast, *Deniega* teaches that tubular membrane 54 is formed generally along the infusion section rather than away from the infusion section. In fact, membrane 54 is located at the infusion section for the specific purpose of allowing fluid flowing within catheter 50 to pass through membrane 54 "substantially uniformly, resulting in substantially uniform flow

through substantially all the exit holes 56" of outer tube 52. See, *Deniega*, paragraph [0057]. As a result, the function of membrane 54, to provide uniform flow to holes 56, requires that membrane 54 be located at the infusion section of catheter 50, adjacent to holes 56, rather than away from said infusion section and away from holes 56. Accordingly, membrane 54 cannot meet the elements of the claimed insert.

Moreover, even if membrane 54 read on the plurality of apertures of the claimed insert, *Deniega* still fails to disclose or suggest the insert comprising a larger diameter portion and an elongated portion having an exterior surface, the exterior surface of the elongated portion of the insert sized relative to the interior surface of the catheter to define a gap between the catheter and the elongated portion of the insert, the larger diameter portion of the insert sized to achieve a snug fit between the interior surface of the catheter and the larger diameter portion of the insert as required, in part, by independent Claims 1, 16 and 23.

Applicants achieve the gap between the catheter and insert by providing, for example, a catheter with an inner diameter of about 3 millimeters and a elongated tube portion of an insert with an outer diameter of about 2.8 millimeters. About one tenth of a millimeter resides therefore between the outer surface of the insert and the inner surface of the catheter. See, Applicants' specification, page 10, lines 16 to 22. Applicants achieve concurrently the snug fit by providing, for example, a larger diameter portion on the insert that has a diameter greater than 3 millimeters, which allows the larger diameter portion to stretch the catheter to make a press tight fit when inserted into the catheter. *Id.* The insert, therefore, can be sized to snugly fit within the catheter while also defining a gap between the insert and catheter to allow for the flushing and lubricating properties described above. FIG. 1 above illustrates the larger diameter portion 38 that sung fits with catheter 10 and elongated portion 32, having a smaller diameter than larger diameter portion 38, which defines a gap between catheter 10 and elongated portion 32 by virtue of the difference in diameters between catheter 10 and elongated portion 32.

By contrast, none of the embodiments taught in *Deniega* have the structure necessary to both achieve a snug fit with the catheter and define a gap between the insert exterior surface and the catheter interior surface. FIGS. 5 to 7 of *Deniega*, shown below, illustrate membrane 54 fitted to outer tube 52 and vice versa. However, *Deniega* fails to disclose or even suggest that any of the embodiments encompassed by FIGS. 5 to 8 define a gap between outer tube 52 and membrane 54.

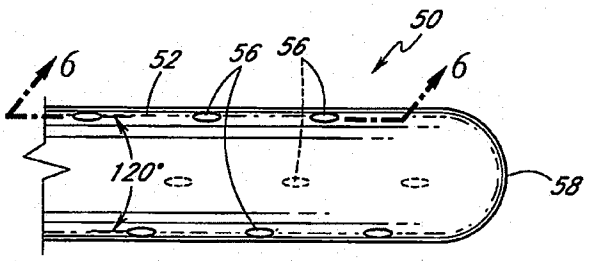


FIG. 5

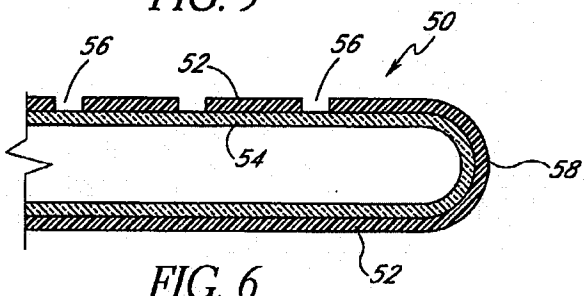


FIG. 6

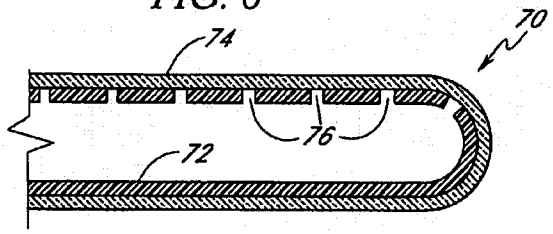


FIG. 7

FIG. 13 of *Deniega*, shown below for example, shows an annular space 208 defined between tube 202 and porous member 206. However, *Deniega* fails to disclose or even suggest that the embodiment of FIG. 13 or any of the similar embodiments encompassed by FIGS. 14 to 18 provide a snug fit between tube 202 and porous member 206.

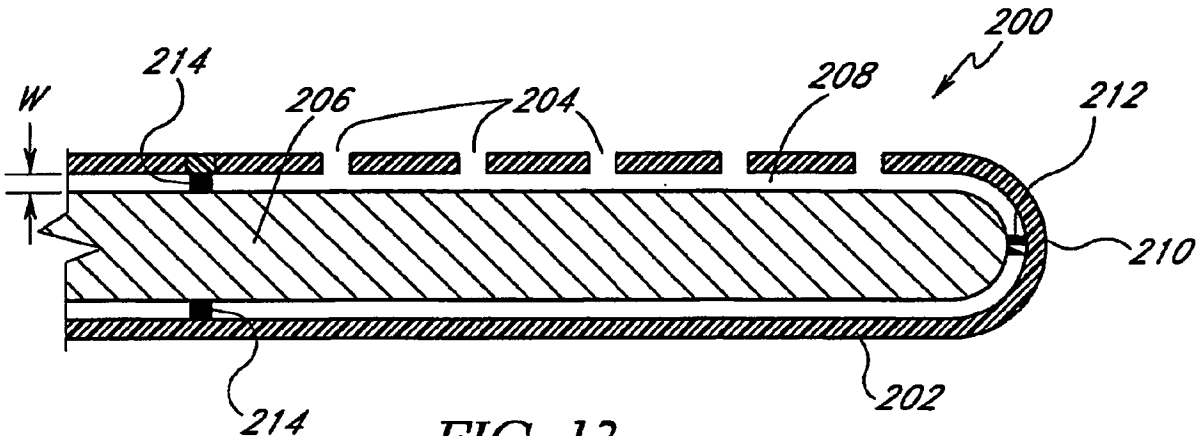


FIG. 13

Applicants submit therefore that *Deniega* fails to disclose or suggest every element of Claims 1, 3, 7 to 10, 14 to 17, 19, 23, 24, 26, 27, 30 and 45. Accordingly, Applicants respectfully request that the anticipation rejection be withdrawn.

Regarding the obviousness rejections of Claims 2, 4, 11, 13, 18, 20 to 22, 28 and 29, Applicants submit that secondary references *Klein, Basta, Bolduc* and *Lazarus*, like primary reference *Deniega*, fail to disclose or suggest the insert of the present claims, specifically an insert that provides a second plurality of side apertures formed on an elongated portion of the insert near an extraperitoneal end of the insert, the elongated portion of the insert having an exterior surface which is sized relative to the interior surface of the catheter to define a gap between the catheter and the elongated portion of the insert, the larger diameter portion sized to achieve a snug fit between the interior surface of the catheter and the larger diameter portion of the insert as required, in part, by independent Claims 1, 16 and 23. Instead, the Office Action relies on the secondary references arguably to recite elements of dependent Claims 2, 4, 11, 13, 18, 20 to 22, 28 and 29.

Moreover, *Klein* is directed to an implant device and a coiled catheter and plug apparatus. See, *Klein*, Abstract, FIGS. 2 and 3, and column 4, lines 18 to 33. *Basta* is directed to a conventional catheter with a cuff and stabilizing device surrounding the catheter and serving as a grip handle for removing the catheter from a subcutaneous location. See, *Basta*, Abstract and paragraphs [0030], [0033] and [0035]. *Lazarus*, like *Klein* and *Basta*, also teaches a conventional catheter. *Lazarus* further teaches use of a stylet or trocar located within the catheter cannula and a steel guide used for positioning the catheter. See, *Lazarus*, Abstract; column 4, lines 3 to 15 and column 5, line 50 to column 6, line 38. The references therefore do not teach or suggest an insert in addition to a conventional catheter.

Bolduc is also deficient because *Bolduc* fails to disclose or suggest the second plurality of side apertures formed on an elongated portion of the insert near an extraperitoneal end of the insert, the elongated portion of the insert having an exterior surface which is sized relative to the interior surface of the catheter to define a gap between the catheter and the insert and achieve a snug fit as required by the claims. Rather than teaching a set of apertures formed on a portion of the insert surrounded by the interior surface of the catheter, *Bolduc* clearly teaches a set of inner tube holes 90 formed beyond the ends of outer tube 30. FIG. 8, illustrated below, clearly shows holes 90 of the inner tube extending beyond the end of the outer tube that is implanted within the total occlusion (TO) of the blood vessel. See, *Bolduc*, paragraph [0079].

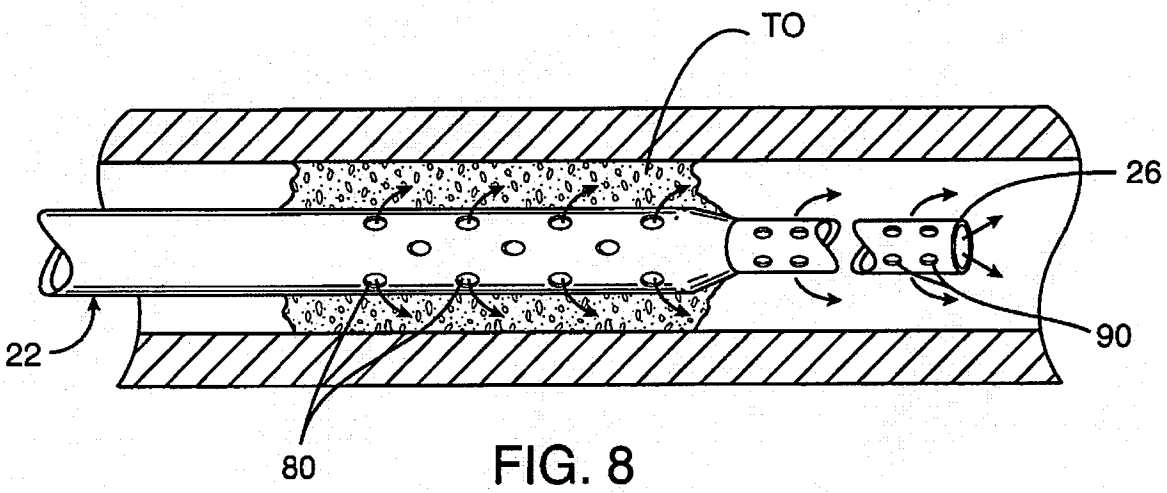


FIG. 8

This configuration of catheter 22 is necessary because holes 80 of the outer tube are designed for delivering therapeutic agent directly to the occlusion while holes 90 on the inner tube provide for blood pumped from one side of the occlusion to pass through the occlusion. See, *Bolduc*, paragraph [0079]. Positioning holes 90 of the inner tube within the outer tube as presently claimed would prevent the catheter of *Bolduc* from functioning for its intended purpose, because blood pumped to and through the inner tube would exit holes 90 onto the occlusion or before the occlusion, thus not allowing the blood to pass through the occlusion to provide blood flow for the patient past the occlusion. As a result, *Bolduc* cannot teach or suggest the insert as presently claimed.

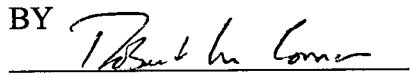
Applicants submit therefore that the cited references, alone or in combination, fail to disclose or suggest every element of Claims 2, 4, 11, 13, 18, 20 to 22, 28 and 29. Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn.

Applicants note that the Examiner has failed to reject or cite evidence in support of a rejection for Claims 5 and 25. As such, Applicants submit that Claims 5 and 25 are allowable as presently recited.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

K&L GATES LLP

BY 

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